MAR 2 6 2012

L&K BIOMED

510(k) SUMMARY

The following 510(k) summary is being submitted as required by 21 CFR 807.92(a):

1. **Submitter:** L&K BIOMED Co., Ltd.
#1104, Ace High-end Tower 3 cha, 371-50, Gasan-Dong,
Geumcheon-gu, Seoul 153-803 Republic of Korea

Contact Person: Hee Kyeong Joo
Telephone. 82-2-2624-1471
FAX .82-2-2624-1477
Email.hkjoo83@gmail.com

Prepared Date January 25, 2012

2. **Device Identification**

Trade Name:	VENUS Spinal Fixation System
Common Name:	Spinal Fixation Appliances
Product Code:	NKB, KWP, KWQ, MNH, MNI
Class	Class III
Classification Name:	1) Spinal Interlaminal Fixation Orthosis, 21 CFR §888.3050 2) Spinal Intervertebral Body Fixation Orthosis, 21 CFR §888.3060 3) Pedicle Screw Spinal System, 21 CFR §888.3070

3. **Identification of Legally Marketed Devices**

L&K BIOMED: VENUS Spinal Fixation System (K100706,K103085)
GS Medical: Anyplus Spinal Fixation System (K091717)
Spine Craft: APEX Spine System (K062513,K092825, K102488)
Stryker Spine: Xia®III Spinal System (K071373,K083393,K091291)
Synthes Spine: USS Polyaixal and Synthes USS Iliosacral System (K022949,K082572)

4. **Device Description**

This system is comprised of screws, set screws, rods, crosslink and connectors. The components of this system are manufactured of Titanium alloy (Titanium-6Aluminum-4Vanadium ELI, per ASTM F136) and CoCrMo alloy (Cobalt-28Chromium-6Molybdenum, per ASTM F1537). The screws are available from 4.0 to 8.5mm diameters with lengths ranging from 20-150mm.

5. **Intended use / Indications for Use**

VENUS Spinal Fixation System is non-cervical spinal fixation devices intended for use as posterior pedicle screw fixation systems (T1-S2/ilium), or as an anterolateral fixation system (T8-L5). All components in the system are limited to skeletally mature patients. These devices are indicated as an adjunct to fusion for all of the following indications regardless of the intended use:

- degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies);
- spondylolisthesis;
- trauma (i.e., fracture or dislocation);
- deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis);
- tumor;
- stenosis, and
- failed previous fusion (pseudoarthrosis)

The VENUS Spinal Fixation System is a pedicle screw system indicated for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

In addition, the VENUS Spinal Fixation System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudoarthrosis).

6. Comparison of the Technology Characteristics

The VENUS Spinal Fixation System shares technological characteristics similar to the predicate devices. These characteristics include similar design, the same materials, substantially equivalent performance characteristics and the same intended use.

7. Performance Data

Non-Clinical Performance and Conclusions:

Bench testing results demonstrate that VENUS Spinal Fixation system performs equivalently to the predicates in static compression bending, static tension, static torsion, dynamic compression bending (in accordance with ASTM F1717-10) and gripping-push down (in accordance with ASTM F1798).

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for this device.

8. Conclusion

The VENUS Spinal Fixation System is substantially equivalent to the device referenced above and is therefore safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

L&K BIOMED Co., Ltd.
% Hee Kyeong Joo
Manager
#1104, Ace High-end Tower 3 cha, Gasan-Dong
Geumcheon-gu Seoul 153-803 Republic of Korea

MAR 2 6 2012

Re: K120270
Trade/Device Name: VENUS Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNH, MNI, KWP, KWQ
Dated: January 25, 2012
Received: January 30, 2012

Dear Hee Kyeong Joo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Director MNM Dep Clin Dir

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K120270

Device Name: VENUS Spinal Fixation System

Indications For Use:

VENUS Spinal Fixation System is non-cervical spinal fixation devices intended for use as posterior pedicle screw fixation systems (T1-S2/ilium), or as an anterolateral fixation system (T8-L5). All components in the system are limited to skeletally mature patients. These devices are indicated as an adjunct to fusion for all of the following indications regardless of the intended use:

- degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies);
- spondylolisthesis;
- trauma (i.e., fracture or dislocation);
- deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis);
- tumor;
- stenosis, and
- failed previous fusion (pseudoarthrosis)

The VENUS Spinal Fixation System is a pedicle screw system indicated for the treatment of severe Spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

In addition, the VENUS Spinal Fixation System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudoarthrosis).

Prescription Use ___√___ AND/OR Over-The-Counter Use _____

(Part 21 CER801 Subpart D) (21 CER801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (OED)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K120270